REMARKS/ARGUMENTS

Applicant has amended the claim language of claim 36 to correct the antecedent basis of that claim, which depends from claim 21. Claims 1, 2 and 21-38 are pending in the present application as amended.

Applicant takes note that the Examiner of Record has changed from Patricia Duffy to Jennifer Graser. The Examiner acknowledged that Applicants had canceled former claims 3-20, which rendered the Species Election between claims 3 and 12 moot. However, the Examiner contends that the newly submitted claims are subject to Restriction Requirement and Species Election. The Examiner alleges that the following are patentably distinct inventions:

Group I. Claims 1, 21-29, and 36-38, drawn to a method of using a purified protein product which is 73 kDa;

Group II: Claims 1, 21-26, 31, 32, and 36-38, drawn to a method of using a purified protein product which is 80 kDa;

Group III: Claims 1, 21-26, and 33-38, drawn to a method of using a purified protein product which is 82kDa.

The Examiner alleged that claim 1 recites a method for selectively inhibiting T-cell rolling in a human host which comprises administering a compound. The Examiner further alleged that the dependent claims recite three compounds which are structurally and biologically distinct, e.g., a 73 kDa protein, an 80 kDa protein, and an 82 kDa protein. The Examiner contends that these three proteins represent different reagents which work in a different manner. The Examiner concluded that these three inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as

capable of use together and they have different designs, modes of operation, and effects (citing MPEP 802.01 and 806.06). The Examiner contends that in the instant case, the different methods recited in Groups I, II and III utilize completely different reagents with different modes of operation and different effects.

In addition, the Examiner alleged that the application contains claims directed to the following patentably distinct species:

Group I.

Species A: a 73 kDa protein comprising SEQ ID NOS: 1, 5, and 6

Species B: a 73 kDa protein comprising SEQ ID NOS: 12, 13, and 14;

Group II:

Species C: an 80 kDa protein comprising SEQ ID NOS 1, 3, and 4

Species D: an 80 kDa protein comprising SEQ ID NOS: 1, 3, and 10

Group III:

Species E: an 82 kDa protein comprising SEQ ID NOS: 1 and 2

Species F: an 82 kDa protein comprising SEQ ID NOS 7, 8, and 9.

The Examiner contends that the species are independent or distinct because each of the methods utilize distinct protein products comprising proteins having different primary structures.

The Examiner required that Applicant elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner found that currently claims 1 and 21-26 are generic.

Applicant respectfully believes that the Examiner has misunderstood the present invention. It is not possible to elect a method of using a purified protein product which is 73 kDa, or 80 kDa, or 82 kDa because that is not the invention described herein. The specification expressly teaches and discloses that the effective agent of the present invention is a compound comprising an immunotherapeutic agent, the immunotherapeutic agent comprising a particulate antigen, and the antigen comprising immunogenic polypeptides of 73, 80 and 82 kDa molecular weight that are to be combined and used together as an immunogen to vaccinate humans. The Examiner is correct that claim 1 recites a method for selectively inhibiting T-cell rolling in a human host which comprises administering a **compound**. However, the Examiner is incorrect in concluding that the dependent claims recite three compounds which are structurally and biologically distinct, e.g., a 73 kDa protein, an 80 kDa protein, and an 82 kDa protein.

The specification teaches and discloses that the compound of the invention comprises an immunotherapeutic agent. It further teaches and discloses that the immunotherapeutic agent comprises an insoluble particulate antigen, and that the insoluble particulate antigen in turn comprises *Leishmania* polypeptides having apparent molecular weights after total reduction and alkylation of about 73 kDa, about 80 kDa and about 82 kDa. Page 16, lines 1-3, for example, discloses that "the immunogen preparations of the second-generation immunotherapeutic agent, which contains protein fractions 3 and 4 obtained after DEAE-chromatography and total reduction and alkylation had three bands with molecular weights of 73, 80 and 82 kDa." Example 17 and Table 18 teach that the fractions used as immunogens that induce clinical remission of psoriatic lesions each contain 73 kD, 80 kD and 82 kDa polypeptides. Claim 21, from which

claims 22-38 depend, is consistent with this disclosure. Claim 21, which depends from claim 1, recites: "the method according to claim 1, wherein **the compound** [of claim 1] includes an immunotherapeutic agent comprising an insoluble particulate antigen derived from isolated killed cells of amastigotes from at least one species of the *Leishmania* genus, the antigen comprising polypeptides having apparent molecular weights after total reduction and alkylation of about 73 kDa, about 80 kDa and about 82 kDa.

Moreover, the specification teaches and discloses that the result or effect of administering the compound comprising the immunotherapeutic agent comprising immunogenic *Leishmania* polypeptides having apparent molecular weights after total reduction and alkylation of about 73 kDa, about 80 kDa and about 82 kDa is to selectively inhibit T-cell rolling in a human susceptible to symptoms of psoriasis. Therefore the 73 kDa, 80 kDa, and 82 kDa polypeptides are combined in the same reagent with the same mode of operation to accomplish the same effect.

Because the present invention claims a compound comprising an immunotherapeutic agent comprising an antigen comprising these immunogenic Leishmania polypeptides, the literature search required would impose no additional burden on the Examiner.

As to the species requirement, the Examiner advised Applicant that a reply to this requirement must include an identification of the group and species elected.

Applicant respectfully urges that it is impossible to elect/identify a group for the reasons given above.

Furthermore, MPEP 803.02 states that if members of a "Markush group are sufficiently few in number or so closely related that a search and examination of the

entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions." Claims 27, 30, and 33 separately recites a Markush group of only two amino acid sequences for each of the 73 kD, 80 kD and 82 kD polypeptides of the invention, respectively. Each subpart of claim 36 recites a Markush group of only two amino acid sequences for each of the 73 kD, 80 kD and 82 kD polypeptides of the invention. Applicant respectfully urges that MPEP 803.02 permits the Examiner to examine these Markush groups as they are small in number even though they are directed to independent and distinct inventions.

In the event the Examiner maintains the species election, Applicant respectfully elects

Species A: a 73 kDa protein comprising SEQ ID NOS: 1, 5, and 6;

Species C: an 80 kDa protein comprising SEQ ID NOS 1, 3, and 4; and

Species E: an 82 kDa protein comprising SEQ ID NOS: 1 and 2

The following claims are readable on the elected species:

1, 21, 22, 23, 24, 25, 26, 28, 31, 34, and 37.

Conclusion

Applicant earnestly solicits early and favorable action by the Examiner. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is respectfully urged to telephone the undersigned at (973) 597-6170. The undersigned also may be contacted via e-mail at blubit@lowenstein.com.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees, which may be required, or credit any overpayment, to Deposit Account No. 501,358.

Respectfully submitted,

Lowenstein Sandler PC

By:

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